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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,940	09/27/2006	Feng Xu	PP019817.0003	4572

27476 7590 06/26/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY- X100B
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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
06/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,940	XU, FENG	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 23-44* is/are pending in the application.

4a) Of the above claim(s) *26,28-33,37 and 39-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,23-25,27,34-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 14-22 have been canceled. Claims 1-13 and 23-44 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-13, 23-29 and 34-40, and the species Shigella in the reply filed on 4-23-09 is acknowledged. Election was made **with** traverse. Applicants' argue the T7 promoter does not function in eukaryotic cells. In particular, applicants argue Moss shows the T7 promoter does not function in eukaryotic cells unless T7 RNA polymerase is present. Applicants' argument is not persuasive. Moss (US Patent 5,126,251) showed the T7 promoter was able to function in eukaryotic cells; therefore, the T7 promoter is "a promoter functional in eukaryotic cells" as claimed.

Claims 26, 28-33, 37, 39-44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4-23-09.

Claims 1-13, 23-25, 27, 34-36 and 38 are under consideration as they relate to the species Shigella.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 23-25, 27, 34-36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The genus of "non-mammalian" host cell in claims 1 and 8 is new matter. "Mammalian" is found in the specification on pg 1, 2 and 18, but the phrase "non-mammalian" cannot be found. Nor is the phrase "non-mammalian cell" implicit from bacteria systems used as DNA vaccine delivery systems described on pg 1, paragraph 3. Applicants point to pg 4, line 29, to pg 6, line 3, and pg 18, lines 13-17. The phrase "non-mammalian cell" encompasses reptilian, avian, amphibian, and other eukaryotic non-mammalian cells while the citations are limited to bacteria, yeast, mycobaceterium, virus and insect cells (it is noted that viruses contemplated by applicants are not cells). Accordingly the scope now claimed is different than the scope contemplated in the specification and is not readily apparent from the scope contemplated in the specification originally filed. As such, the phrase "non-mammalian" is new matter.

The phrase "promoter functional in eukaryotic cell" in claims 1 and 8 is new matter. While "eukaryotic" is found in the specification on pg 1, end of 3rd paragraph, pg 4, 2nd full paragraph, line 3, and pg 6, 3rd paragraph, line 5, the scope of promoters functional in eukaryotic cells cannot be found. Applicants point to pg 6, lines 9-13, for support. Applicants' argument is not persuasive. The citation relates to a polynucleotide sequence encoding the immunogen cloned into SalI and EcoRI

restriction sites of a eukaryotic expression vector, pCMVKm2, which contains a CMV promoter and bGH terminator. The citation in no way implies applicants contemplated the broad genus of promoters now claimed.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 5-8, 10, 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Summoto (Int. J. Cancer, 1997, Vol. 73, pg 556-561) has been withdrawn in view of the limitation of "non-mammalian host cell."

The rejection of claims 1, 3, 5-8, 10, 12 and 13 under 35 U.S.C. 102(a) as being anticipated by Kojima (Human Gene Therapy, May 20, 2003, Vol. 14, pg 715-728) has been withdrawn in view of the limitation of "non-mammalian host cell."

The rejection of claims 1, 5-8, 12 and 13 under 35 U.S.C. 102(a) as being anticipated by Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) has been withdrawn because Xu taught the attenuated Shigella expressed low amount of Gag protein "using its own machinery".

The rejection of claims 1, 2, 5-9, 12 and 13 under 35 U.S.C. 102(a) as being anticipated by Li (J. Allergy Clin. Immunol. July 2003, Vol. 112, pg 159-167) has been withdrawn because Li relates to E. coli and does not relate to the elected species (Shigella).

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-8, 9, 12, 13, 23-25, 27, 34-36 and 38 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) as

supported by zur Megede (J. Virol. 2000, Vol. 74, pg 2628-2635) in view of Masschalck (Applied and Environmental Microbiology, Vol. 67, No. 1, pg 339-344) and Raettig (Zentralblatt fuer Bakteriologie Mikrobiologie und Hygiene 1 Abt originale A, 1981, Vol. 205, No. 4, pg 511-520, abstract only).

Xu administered attenuated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen (pg 644-645, section 2.1; pg 645-646, section 3.1). The Shigella were attenuated because they had mutant genes (pg 644, col. 2, section 2.1). The promoter used to express the antigen was a CMV promoter as supported by zur Megede (pg 2629, col. 1, line 17), which is "a promoter functional in a eukaryotic cell." Xu did not teach the cell was "unable to use its own machinery to express the encoded immunogen" or inactivating the cells.

However, Masschalck inactivated Shigella using lysozyme under hydrostatic pressure, and Raettig heat inactivated Shigella. These techniques inherently result in Shigella to be "unable to use its own machinery to express the encoded immunogen" as claimed because the cells are inactivated.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to administer Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by Xu using Shigella that had been inactivated using lysozyme treatment described by Masschalck or heat inactivation described by Raettig. Those of ordinary skill would have been motivated to inactivate Shigella using lysozyme treatment described by Masschalck or heat inactivation described by Raettig instead of merely

attenuating the cells to prevent replication of the cells, prevent infection, and prevent dysentery.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

2. Claims 1-13, 23-25, 27, 34-36 and 38 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) as supported by zur Megede (J. Virol. 2000, Vol. 74, pg 2628-2635) in view of Masschalck (Applied and Environmental Microbiology, Vol. 67, No. 1, pg 339-344) and Raettig (Zentralblatt fuer Bakteriologie Mikrobiologie und Hygiene 1 Abt originale A, 1981, Vol. 205, No. 4, pg 511-520, abstract only) as applied to claims 1, 2, 5-8, 9, 12, 13, 23-25, 27, 34-36 and 38 and further in view of Chang (Applied and environmental microbiology, June 1985, Vol. 49, No. 6, pg 1361-1365, abstract only), Kruithof (Proceedings – Annual Conference, American Water Works assoc. 2000, pg 331-344, abstract only) and the applicant-acknowledged art at the time of filing.

The combined teachings of Xu, Masschalck and Raettig taught administering heat inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice to generate an immune response against the antigen (see obviousness rejection above). The combined teachings of Xu, Masschalck and Raettig did not teach the cell was inactivated using UV light exposure or hydrogen peroxide.

However, Chang taught inactivating Shigella using UV light exposure (see abstract) and Kruithof inactivated a variety of bacteria using UV light exposure. Furthermore, applicants acknowledge that inactivating cells was standard in the art at the time of filing including UV light exposure (pg 6, lines 17-19). These techniques inherently result in Shigella to be "unable to use its own machinery to express the encoded immunogen" as claimed because the cells are inactivated.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to administer inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by the combined teachings of Xu, Masschalck and Raettig using UV light treatment as described by Chang and Kruithof and acknowledged by applicants as being known in the art. It also would have been obvious to those of ordinary skill in the art at the time the invention was made to administer inactivated Shigella comprising a plasmid encoding HIV-1 SF2 Gag to mice, which generated an immune response against the antigen as described by the combined teachings of Xu, Masschalck and Raettig using hydrogen peroxide treatment as described by Kruithof and acknowledged by applicants as being known in the art. Those of ordinary skill would have been motivated to inactivate Shigella using UV light treatment or hydrogen peroxide instead of heat inactivation because Kruithof taught UV treatment and hydrogen peroxide the "ultimate solution for pesticide control and disinfection" (see title).

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner